

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

)
ASTELLAS INSTITUTE FOR REGENERATIVE)
MEDICINE, and STEM CELL & REGENERATIVE)
MEDICINE INTERNATIONAL, INC.,)
)
Plaintiffs,) C.A. NO. 1:17-cv-12239-ADB
)
v.) **ORAL ARGUMENT REQUESTED**
)
IMSTEM BIOTECHNOLOGY, INC., XIAOFANG) [REDACTED]
WANG, and REN-HE XU,)
)
Defendants.) [REDACTED]
)

**DEFENDANTS' OPPOSITION TO
PLAINTIFFS' OMNIBUS MOTION *IN LIMINE***

Pursuant to this Court's Amended Scheduling Order and Pretrial Order dated September 26, 2019 (Dkt. 106), Fed. R. Civ. P. 7, and L.R. 7.1, Defendants Imstem Biotechnology, Inc. ("Imstem"), Xiaofang Wang ("Wang"), and Ren-He Xu ("Xu") (collectively "Defendants") hereby file their opposition to Plaintiffs' Omnibus Motion *in Limine* (Dkt. 170).

I. PRECLUDING EXPERT TESTIMONY FROM DRS. WANG AND XU

In an inventorship dispute in which one of the central questions is whether the parties' various contributions were merely "well-known concepts," *see Israel Bio-Eng'g Project v. Amgen, Inc.*, 475 F.3d 1256, 1263-64 (Fed. Cir. 2007) (test for joint inventorship), the parties' fact testimony will necessarily be highly expert. The named inventors of the '551 patent, experts in the field of their own patent, are themselves uniquely poised to compare what they contributed to the prior art. Whether that comparison is characterized as fact or opinion, Defendants Wang and Xu must be given latitude to explain the state of the art as they knew it

and why their contributions differed from it. Plaintiffs' motion should be denied because it is without merit, is unripe, and seeks relief to which Plaintiffs are not entitled.

A. Background

This patent case is a highly complex, science-driven, inventorship dispute concerning the differentiation of human embryonic stem cells. Several of the fact witnesses for each party are highly knowledgeable in their field, such that factual knowledge is often indistinguishable from expert testimony. Indeed, Plaintiffs acknowledge the conundrum in their own motion, noting that fact witnesses of both parties will need to testify about "details about experiments they performed, scientific articles or papers about which they personally were aware of at relevant times, or relevant events or exchanges that occurred, which themselves are technical in nature." (Dkt. 170 at 7, n.2). Plaintiffs have elsewhere acknowledged the blurred line by designating portions of the deposition transcript of Dr. Jianlin Chu, Ph.D, a former Plaintiff employee,¹ in which they objected to the questions on the grounds that they called for expert opinions. *See Ex. 1* (Chu Depo. Tr.) at 35:3-11; 181:1-16.² The designation of testimony that Plaintiffs recognize as expert only underscores the confluence of facts and expertise in this case. Recognizing this, Defendants took the precaution of designating Drs. Wang and Xu pursuant to Fed. R. Civ. P. 26(a)(2)(C). Plaintiffs did not designate Drs. Kimbrel or Lanza experts.

B. Argument

As Plaintiffs seem to acknowledge, Drs. Wang and Xu were not required to prepare a report because neither were specially engaged for this litigation and neither is an employee of

¹ Because she is no longer employed by Plaintiffs, the parties have agreed to designate her deposition testimony at trial (rather than calling her live). Defendants' inability to cross-examine Dr. Chu on her testimony at trial stands in stark contrast with their ability to do so with respect to Drs. Xu and Wang's testimony.

² All exhibits are attached to the Decl. of Timothy Shannon in Supt. of Defs. Oppn. to Pltfs' Omnibus Mot. *in Limine* ("Shannon Decl.").

Imstem with duties that include regularly providing expert testimony. *See Fed. R. Civ. P. 26(a)(2)(B).* As such, they were designated pursuant to Fed. R. Civ. P. 26(a)(2)(C), which does not require a written report. Disclosure under Rule 26(a)(2)(C)

is considerably less extensive than the report required by Rule 26(a)(2)(B). Courts must take care against requiring undue detail, keeping in mind that these witnesses have not been specially retained and may not be as responsive to counsel as those who have.

Rule 26 Advisory Committee Notes (2010 Amendment). Defendants have fulfilled the requirements of Rule 26(a)(2)(C) by providing Plaintiffs with the subject matter and a summary of the facts and opinions of Drs. Wang and Xu.

Specifically, Plaintiffs were aware as early as the initial disclosures that the subject matter of the testimony of Drs. Wang and Xu would include scientific, technical and specialized knowledge. Indeed, in the Defendants' Initial Disclosures, Dr. Wang was identified as a witness who would testify to "the invention and reduction to practice of the inventions claimed in the patents-in-suit." Ex. 2 (Def.'s Initial Disclosures). Dr. Xu was identified as a witness who would testify to "the conception and reduction to practice of the inventions claimed in the patents-in-suit." *Id.* In addition, Defendants answered multiple sets of interrogatories propounded by Plaintiffs, including interrogatories related to Drs. Wang and Xu's knowledge of autoimmune diseases, their research related thereto, and the patents and inventions related to this lawsuit. Ex. 3 (Def.'s Objections and Resp. to Pltfs' First Set of Interrogatories at No. 15; Defendant Ren-He Xu's Responses and Objections to Astellas' Second Set of Interrogatories (Nos. 22-30) at Nos. 23 and 27; Defendant Xiaofang Wang's Responses and Objections to Astellas' Second Set of Interrogatories (Nos. 22-30) at Nos. 23 and 27). These interrogatory responses also incorporated by reference, for example, Dr. Wang's CV, which was produced to Plaintiffs long ago.

Thereafter, Plaintiffs deposed Drs. Wang and Xu on two separate occasions, generating hundreds of pages of transcripts. During the depositions, Plaintiffs asked numerous questions that amply demonstrated Plaintiffs' understanding that Drs. Wang and Xu had specialized knowledge regarding the claims.

Q. My question is, do you agree that the Astellas scientists were the first to culture MSCs via a hemangioblast intermediate?

A. No, I don't agree on that.

Q. And why don't you agree on that?

A. Because there are papers published several years ago, before 2010, and people have been using hemangioblast-derived MSCs. So hemangioblast to MSCs is not the first to develop by a scientist, no.

Q. Who do you believe first developed hemangioblast-derived MSCs?

A. So there's a professor of University of Wisconsin, named Igor Slukvin. I-g-o-r, S-l-u-k-v-i-n. They published in 2008, and they have a patent on that as well.

Ex. 4 (Wang Depo. Tr.) at 74-75. Dr. Wang knew what others in the art knew and had done, and knew – or arguably had an opinion – that Plaintiffs were not the first to invent their alleged invention because it existed in the prior art.

Such testimony, along with Defendants' Initial Disclosures and answers to interrogatories, made clear that Drs. Wang and Xu were and are experts with relevant, admissible expert opinions. As such, on October 4, 2019, Defendants designated Drs. Wang and Xu as experts to testify consistently with their depositions. (Dkt. No. 175-1.) Given the volumes of information provided to Plaintiffs, including two opportunities to depose each of these doctors, it is unbelievable that Plaintiffs now complain that the designation was insufficient to provide them with fair notice of Drs. Xu and Wang's expert testimony.

In addition, Plaintiffs' efforts to exclude Drs. Wang and Xu based on what Plaintiffs claim is an inadequate expert designation is, essentially, an improper – and unripe – discovery motion. Plaintiffs do not seek to exclude Drs. Wang or Xu because they are unqualified or unhelpful to the jury. Indeed, Plaintiffs acknowledge that their own witnesses will need to provide much the same type of testimony as Drs. Wang and Xu (despite Plaintiffs never designating their own witnesses as experts). *See Mem. Of Law in Support of Omnibus Motion in Limine* (Doc. 170) at 7, n. 2. Rather, their sole complaint is that the designation provided during discovery was purportedly inadequate.

Thus, even if the designation were inadequate (it is not), the proper remedy was for the Plaintiffs to seek a discovery conference pursuant to Local Rule 37.1 to attempt to narrow or resolve this purported issue with Defendants. *See Hasbro, Inc. v. Serafino*, 168 F.R.D. 99, 101 (D. Mass. 1996) (before filing any discovery motion the moving party must arrange for a discovery conference with opposing counsel); *see also* Local Rule 26.2(c) (“the judicial officer shall not consider any discovery motion that is not accompanied by a certification, as required by L.R. 7.1(a)(2) and L.R. 37.1(b), that the moving party has made a reasonable and good faith effort to reach agreement with opposing counsel...”).³ Plaintiffs never sought a conference. Plaintiffs’ failure to follow Local Rules 26.2(c) and 37.1 is fatal:

[T]he purpose of a full consultation pursuant to Local Rule 37.1(A) is to enable the parties to attempt to narrow, if not resolve, their dispute. It is not up to the Court to expend its energies when the parties have not sufficiently

³ Plaintiffs rely, in part, on a case that was before this Court, *CardiaAQ Valve Technologies v. Neovasc, et al.*, Civil Action No. 14-12405, 2016 WL 8203206 (D. Mass. April 25, 2016). Notably, in *CardiaAQ*, the defendant attempted to obtain more information regarding the designation prior to seeking the expert’s exclusion. *Id.* at Dkt. 342-1 (CardiaAQ responding to Neovasc’s position regarding adequacy of expert designation). Here, there were no such communications from Plaintiffs regarding the purported insufficiency of the designation. In addition, after finding that the expert had expertise in “transcatheter mitral valve replacement devices,” the Court excluded his testimony only for “certain issues identified in his expert disclosure, including general industry customs beyond his own personal experience and CardiaAQ’s damages.” *Id.* at *3. Further issues regarding his testimony were reserved for trial. *Id.* (“Other rulings may be made at trial as the presentation of evidence warrants”). In short, *CardiaAQ* does not stand for the broad proposition that expert testimony of the nature at issue here should be broadly excluded.

expended their own.

Id. The Plaintiffs cannot at this belated stage of the case ask the Court to expend its energies when they made no effort to expend their own.⁴

Assuming, *arguendo*, that the motion is ripe and that the designation is inadequate, the proper remedy is to order Defendants to amend the designation, not exclude the experts. Indeed, the vast majority of the cases cited by Plaintiffs ordered that the designations be amended, not that the experts be precluded from testifying. *See Emerson Electric Co. v. Suzhou Cleva Electric Appliance Co., Ltd.*, 2015 WL 8770712, *3 (E.D. Mo. 2015) (providing the designating party an opportunity to amend disclosures); *Ingram v. Novartis Pharm. Corp.*, 282 F.R.D. 563, 565 (ordering designating party to provide disclosure of Rule 26(a)(2)(C) experts); *Luminara Worldwide, LLC v. Liown Electronics, Co., Ltd.*, 2016 WL 6920516, *3 (D. Minn. 2016) (ordering supplemental disclosure of Rule 26(a)(2)(C) experts); *Cordero v. Froats*, 2016 WL 7426577, * 8 (D.N.M 2016) (despite short time remaining before trial, court ordered the party offering Rule 26(a)(2)(C) experts to provide additional information if they intended to elucidate expert testimony from the subject witnesses). In *Hayes v. American Credit Acceptance, LLC*, 2014 WL 3927277, *4 (D. Kan. 2014), also cited by Plaintiffs, the court held that:

Plaintiffs' disclosures put the defendants on notice generally that the treating physicians would be testifying their conduct caused plaintiffs' medical conditions to worsen. Despite the disclosures' lack of specificity, defendants should not be surprised by this line of anticipated testimony. Moreover, any prejudice resulting from the lack of specificity can be cured by allowing plaintiffs to supplement their disclosures.⁵

⁴ Plaintiffs argue that any suggestion that they could have deposed Drs. Wang and Xu a third time is meritless because they could not have known the topics on which the doctors would testify. If Plaintiffs' complaint regarding the designation were in good faith, they would have followed Rule 37.1 to clarify the issue instead of springing this issue on the Court at the 11th hour.

⁵ Plaintiffs cite *Thibeault v. Square D. Co.*, 960 F.2d 239 (1st Cir. 1992) to argue that the designation of Drs. Wang and Xu would allow discovery to "degenerate into a game of cat and mouse." *Thibeault* is easily distinguished from

Here, Plaintiffs were on notice no later than October 4, 2019 that Drs. Wang and Xu would testify as experts. In fact, through Defendants' Initial Disclosures, answers to interrogatories, and deposition testimony, Plaintiffs were on notice that Drs. Wang and Xu were experts long before the official designation. Thus, Plaintiffs should not be surprised that Drs. Wang and Xu will testify to expert opinions. Even if they can establish surprise, any prejudice to the Plaintiffs is cured by supplementation of the designations.

In sum, there is no basis for excluding the expert testimony of Drs. Wang and Xu. Plaintiffs were sufficiently on notice of the intent to call Drs. Wang and Xu as experts and waited until the eve of trial to claim that the designation was insufficient. Under the circumstances, the motion should be denied or, in the alternative, Defendants should be given an opportunity to supplement the designation of Drs. Wang and Xu.⁶

II. PRECLUDING ARGUMENT THAT PATENT EXAMINERS ARE EXPERTS

Plaintiffs style the next section of their motion (Br. at 7) as seeking to preclude Defendants from offering "evidence," through Defendants' expert, Bryan Zerhusen, Ph.D, that "examiners with the [PTO] are experts on a particular subject matter or experts in general."

this case. In *Thibeault*, plaintiff answered an expert interrogatory by stating that experts had not been selected and that plaintiff reserved the right to timely supplement prior to trial. *Thibeault*, 960 F.2d at 241. Two years later – on the eve of trial – plaintiff finally supplemented the interrogatory answer and designated witnesses. *Id.* By that point, the case had been set for trial for almost a year, was already on a trial list, and, on the day before the designation, the court had informed the parties that the trial would start in five days. *Id.* 960 F.2d at 241-242. Conversely, Drs. Wang and Xu were designated on the deadline for expert designations, months before trial. If Plaintiffs felt that the designation was insufficient, which Defendants deny, they had months to seek clarification directly from the Defendants in accordance with the Local Rules and, if that failed, to seek intervention of the Court. If either party is playing "cat and mouse," it is Plaintiffs who waited to raise this discovery issue until the eve of trial.

⁶ Regardless of the Court's decision, Plaintiffs' fact witnesses should be precluded from offering expert testimony because they were not designated as experts. It would be wholly unfair to penalize Defendants by precluding expert testimony from Drs. Wang and Xu despite being designated as experts, while allowing witnesses who were not designated as experts to render expert opinions. If the instant motion is denied, the status quo remains, and witnesses who were designated may render expert opinions while those who were not designated may not. If the Court orders Defendants to amend their designation, the Plaintiffs cannot also amend because they never designated any Rule 26(a)(2)(C) witnesses.

(*Id.*). Plaintiffs use the term, “expert,” in a variety of ways in their motion: sometimes with respect to the science (“in the particular area of stem cells”) (Br. at 8), and sometimes with respect to the decisions made by the PTO Examiner during prosecution of the ‘551 patent (“diligence or skill”). (*Id.*). The ambiguity reflects Plaintiffs’ apparent desire to preclude a broad swath of testimony from Dr. Zerhusen, while allowing themselves room to negatively characterize the patent examination process through cross examination.⁷

As a starting point, Plaintiffs have never seriously challenged Dr. Zerhusen’s credentials or that he is an expert in “patent prosecution.”⁸ Dr. Zerhusen is the Chair of the Life Sciences Practice Group at Cantor Colburn LLP, which is one of the leading patent prosecution firms in the nation. He has specialized in U.S. and international patent prosecution for 15 years, prosecuting hundreds of patents. (*See* Ex. 5 (Zerhusen Expert Report) at ¶¶ 1-2; *see also id.* at Exhibit 1 (curriculum vitae)). He holds a Ph.D. in Cell Physiology and Biophysics, completed a postdoctoral fellowship, and has worked as a research scientist. (*Id.* at ¶ 1). There is no dispute that Dr. Zerhusen is “an expert in the field of patent prosecution,” particularly in the life sciences. (*Id.* at ¶ 2).

At trial, Dr. Zerhusen will, among other things, explain to the jury some of the arcana of PTO patent prosecution – how applications are filed, how the PTO examines them, what a rejection is, what an allowance is, etc. – and the meaning of various documents in the ‘551 patent prosecution history. This is proper expert testimony. *See Bausch & Lomb, Inc. v. Alcon Labs.*,

⁷ Plaintiffs also point to two snippets from Defendants’ reply summary judgment brief, which are attorney argument – not evidence. To the extent that Plaintiffs seek, in their motion, to prevent Defendants’ counsel from arguing to the jury its view of the evidence, Plaintiffs’ request under Fed. R. Evid. 602 and 702 (which are directed to “evidence” and expert “testimony”) does not make sense. Certainly, counsel for Defendants – like counsel for Plaintiffs – is entitled to present to the jury their perspective on what the “evidence” means and shows. That the parties draw different conclusions from the PTO Examiner’s statements does not mean that those different views should be excluded under Plaintiffs’ motion *in limine*.

⁸ Dr. Zerhusen is the only expert in this case who is qualified to testify about PTO practice and procedure; Plaintiffs could have (but apparently chose not to) have their own expert.

Inc., 79 F.Supp.2d 252, 256 (W.D.N.Y. 2000) (“Obviously PTO procedures are foreign to the average person, and it may be helpful to the jury to hear someone experienced in those procedures to explain how they operate in terms that a layperson can understand”); *see also Power Integration, Inc. v. Fairchild Semiconductor Int’l, Inc.*, C.A. No. 04–1371–JJF, 2009 WL 1649414, at *1 (D. Del. June 11, 2009) (allowing evidence of USPTO practice and procedure that “effectively summarizes the factual record”); *Szoka v. Woodle*, No. C 02-5524 SI, 2004 WL 5512964, at *3 (N.D. Cal. June 7, 2004) (“Given the complexity of patent litigation, courts have regularly permitted expert testimony by patent attorneys on a range of issues, including proceedings before the [PTO]”).

Pertinent to Plaintiffs’ motion, Dr. Zerhusen will translate what the PTO Examiner stated in his “Reasons for Allowance” for the ‘551 patent and – based on his training and experience – explain what the Examiner’s statements mean in layman’s terms. (Ex. 5 at ¶¶ 24-25).⁹ The Examiner identified the GSK-3 inhibitor limitation in finding that Drs. Wang and Xu’s claim amendments “overcome[] the rejections of record.”¹⁰ In essence, Dr. Zerhusen will testify that the entity charged with evaluating and granting patents (the PTO) found that a particular aspect of the ‘551 patent, namely the GSK-3 inhibitor limitation, was sufficient to overcome the Lanza/Kimbrel application that became the ‘321 and ‘956 patents. It is this evidence, which is central to the inventorship dispute, the Plaintiffs seek to sideline.¹¹ By explaining the PTO

⁹ Paragraphs 24-25 are the only portions of Dr. Zerhusen’s Expert Report that Plaintiffs specifically take issue with in their Motion. Plaintiffs’ counsel never asked Dr. Zerhusen about paragraph 24 during his deposition. Although Plaintiffs attached a portion of that testimony relating to paragraph 25, Defendants attach it here in full. (See Ex. 6 (Zerhusen Dep. Tr.) at 66:12- 71:14).

¹⁰ The “rejections of record” was the Lanza/Kimbrel patent application that matured into the ‘321 and ‘956 patents, as well as certain art that was used for an “obviousness combination” with that application. (Ex. 5 at ¶ 22). In response to the Examiner’s prior art rejections, the Defendants amended the ‘551 patent claims to require the “GSK-3 inhibitor step” (previously, it was optional). (*Id.* at ¶ 23).

¹¹ Ironically, Plaintiffs are seeking to suppress Dr. Zerhusen’s testimony that is strikingly similar to what they have sought from other witnesses. Plaintiffs have designated deposition testimony from Defendants’ patent prosecutor,

Examiner's statements in terms that the jury can understand, and putting them in context of PTO practice and procedure, Dr. Zerhusen does not "imbue [the Examiner's statements] with the force of expert testimony." (Br. at 7).¹² Rather, Dr. Zerhusen is offering his own expert testimony.

During his 15 years of prosecuting patents, Dr. Zerhusen has had innumerable experiences with PTO Examiners. He articulates his views on the PTO and Examiners, based on his experience, in paragraph 14 of his Expert Report,¹³ and again in response to questions from Plaintiffs' counsel at his deposition. For example, Dr. Zerhusen testified that "based on his personal experience," PTO Examiners "in the biotechnology art units" are "highly trained in the area of biotechnology/biochemistry" (*See* Ex. 6 at 94:8-22). He also testified that, in his experience, PTO Examiners in the biotechnology art units "tend to be very capable and competent of understanding the technology," including in their "ability to search, raise objections, identify issues, and to appreciate counter arguments and claim amendments." (*Id.*) This is all acceptable background for his opinion.

The allegedly objectionable deposition testimony that Plaintiffs cite arose when their counsel asked Dr. Zerhusen whether he had personal knowledge of the particular PTO Examiner that issued the '551 patent – and Dr. Zerhusen readily admitted he did not. (*See* Br. at 6 (citing

Suzie Cheng, Ph.D, in which Plaintiffs asked Dr. Cheng a leading question that articulated exactly what Dr. Zerhusen's testimony will suggest – that the presence of the GSK-3 inhibitor limitation in the amended claims was the sole stated reason for allowance of the '551 patent over the prior art of record (*i.e.* the Lanza/Kimbrel application). *See* Ex. 7 (Cheng Dep. Tr.) at 300:25-302:6 ("Q. The only reason that the examiner allowed the claims is that they require the presence of a GSK-3 inhibitor at a specific concentration that results in the production of hES-MSCs with specific characteristics; is that correct?). Plaintiffs should not be allowed, on the one hand, to introduce Dr. Cheng's testimony in response questions from their counsel about the PTO Examiner's "reasons," as stated in the prosecution history, but not allow Defendants to question Dr. Zerhusen – who, unlike Dr. Cheng, has been designated an expert in this case on precisely this issue – to offer his expert opinion on PTO practice and procedure and to explain the PTO Examiner's statements in his Reasons for Allowance.

¹² Both sides have separate experts (Dr. Ali Brivanlou and Dr. John Perry) that offer opinions on whether the addition of the GSK-3 inhibitor limitation of the '551 patent is an "inventive feature."

¹³ Plaintiffs' Motion does not discuss Paragraph 14 of Dr. Zerhusen's Expert Report, nor does the Motion specifically seek to preclude such testimony.

deposition testimony)).¹⁴ That Plaintiffs' counsel asked questions that "opened the door" to Dr. Zerhusen testifying about his own experiences with the PTO and Examiners, does not somehow transform his opinion into one that states that the PTO Examiner who allowed the '551 patent is an "expert." *See, e.g.*, Ex. 6 at 41:25-43:2, 94:8-95:3. Plaintiffs cannot ask Dr. Zerhusen pointed questions at deposition and then use his responses to bootstrap an argument as to what Plaintiffs contend his "opinion" in this case actually is. Moreover, Plaintiffs are free to ask Dr. Zerhusen questions on cross (as they did during the deposition) to make clear that his experiences vary across Examiners, and that he is speaking in general terms – and not about the particular Examiner who allowed the '551 patent. (*See id.*) Plaintiffs' potential cross examination does not make Dr. Zerhusen's testimony improper in the first instance

As explained above, Plaintiffs' motion *in limine* should be denied, and Defendants should be allowed to elicit testimony from Dr. Zerhusen consistent with his opinions in his expert report, including in paragraphs 24-25, and at his deposition.¹⁵

III. PRECLUDING EVIDENCE AND REFERENCES TO MATHEW VINCENT'S STATUS WITH THE MASSACHUSETTS BAR

Plaintiffs' argument with respect to Matthew Vincent is ambiguous. At first, Plaintiffs style their argument as a request to preclude evidence regarding Mr. Vincent's "status." (Br. at

¹⁴ There is no Fed. R. Evid. 602 or 702 problem. Plaintiffs' argument in this regard is based upon a fundamental misunderstanding of Dr. Zerhusen's expert testimony. He is not offering any opinion on the particular PTO Examiner's "skill thoroughness, training or expertise." (Br. at 8). Rather, in response to Plaintiffs' questions at deposition, Dr. Zerhusen testified about his professional experience with the PTO and Examiners in general.

¹⁵ During Dr. Zerhusen's deposition, Plaintiffs suggested they would argue that Examiners are incompetent and it would offer statistics about patents being invalidated in litigation or at the Patent Trial & Appeal Board ("PTAB"). *See, e.g.*, Ex. 6 at 42:44:13, 73:2-25, 77:11-79:24. It would be unfair to prevent Dr. Zerhusen from offering his opinions about PTO practice and procedure, but allow Plaintiffs to elicit testimony to undermine the PTO or the Examiner. To the extent that the Court allows Plaintiffs' motion, Plaintiffs should be precluded from offering "evidence" that the PTO are not experts on a particular subject matter or experts in general, and further from denigrating the PTO, including allowing Plaintiffs evidence regarding the lack of qualifications of PTO Examiners, the time limits allowed for examinations, and the nature and number of patents that get invalidated at the PTAB or in litigation. *See, e.g.*, *DNT, LLC v. Sprint Spectrum LP*, Civ.A.No. 3:09-21, 2009 WL 5842058, at *1 (E.D. Va. Dec. 1, 2009) (granting motion *in limine* to preclude evidence "tending to disparage the Patent and Trademark Office").

9). Later, they seek to preclude evidence of his disciplinary hearing and “disbar[ment].” (*Id.* at 10). Later they seek to preclude evidence of his *ever* having had a law degree. (*Id.* at 11 (no reference to “former lawyer”)).

To the extent Plaintiffs are seeking to exclude evidence of Mr. Vincent’s misconduct and resignation from the Massachusetts Bar, Defendants have no quarrel. Unless Plaintiffs open the door, Defendants have no intention of offering evidence concerning Mr. Vincent’s disciplinary hearing or resignation.

To the extent Plaintiffs are seeking to exclude evidence that Mr. Vincent was “a former lawyer” or “one-time lawyer” on the other hand – a statement that can be made to the jury without ornamentation or sinister suggestion – Defendants object.¹⁶

Mr. Vincent was a key player in Plaintiffs’ [REDACTED] before the three-year statute of limitations. His emails, which may be brought into evidence via other witnesses and/or as party admissions, are sufficient to establish [REDACTED] [REDACTED]. Plaintiffs have admitted that in early 2014 they discovered the ‘551 PCT Application that would mature into the ‘551 Patent. Am. Compl. at ¶ 62 (“On February 4, 2014, Plaintiffs first became aware of WO2014/011407, an international patent application having a similar disclosure as the ’551 patent.”).¹⁷ On February 21, 2014, Mr. Vincent [REDACTED]

¹⁶ Another variation, if the Court prefers, is that Mr. Vincent had “a law degree.”

¹⁷ Plaintiffs’ use of the word “similar” in describing the international and the PTO applications is coy, at best. As Dr. Zerhusen explains in his expert report, the two applications are – and must be – identical, such that all information in the specification of one is in the specification of the other. (*See* Ex. 5 at ¶¶ 32-36).

¹⁸ Ex. 8 (Metadata re email from Mary Lee Fleishell to Erin Kimbrel and others (February 21, 2014) (AIRM00037250)); Ex. 9 (Plaintiffs’ Privilege Log, p. 10 (dated July 29, 2019), line item #309).

In a lengthy June 2014 email exchange, Mr. Vincent, then acting as Vice President of Business Development,¹⁹ wrote [REDACTED]

.20

21

Mr. Vincent wrote later that day:

22

Approximately twenty minutes later, Mr. Vincent wrote:

23

¹⁹ Mr. Vincent worked for Advanced Cell Technologies (“ACT”) the predecessor company to the Plaintiffs. ACT was later acquired by Astellas, which later also acquired co-Plaintiff SCRMI. For purposes of the instant Motion, we use the terms ACT, Astellas, and Plaintiffs interchangeably.

²⁰ The emails were titled, [REDACTED] See Ex. 10 (first of many emails among Matthew Vincent, Mike Heffernan, Robert Lanza, and others (June 5, 2014);

²¹ Ex. 11 (Email from Matthew Vincent to Mike Heffernan (June 5, 2014 3:25 PM) (AIRM00097111 at 112 -13)) (emphasis added).

²² *Id.* at AIRM00097111

²³ Ex. 12 (Email from Matthew Vincent to Mike Heffernan (June 5, 2014 8:39 PM) (AIRM00097117)).

In short, by June 2014 Plaintiffs knew that [REDACTED]

[REDACTED] *Id.*

Mr. Vincent's status as a former lawyer – his legal training – is probative of how thoroughly Astellas understood its claims. It was no mere layperson who [REDACTED]. It was a lawyer, one with extensive training in intellectual property. Because of that training, Mr. Vincent was immediately able to [REDACTED]
[REDACTED]. Mr. Vincent's legal training (especially in intellectual property law) is key to understanding how much Plaintiffs knew before the three-year statute of limitations window.²⁴

In sum, while the fact and reason Mr. Vincent's departure from the Bar is arguably not relevant, his experience as an attorney certainly is. A simple reference to Mr. Vincent being a former lawyer with training in intellectual property law will not – without more – stir the jury's curiosity. Mr. Vincent's legal training can be presented without an undue risk of unfair prejudice.²⁵

IV. PRECLUDING DEFENDANTS FROM USING PLAINTIFFS' PRIVILEGE LOG AS EVIDENCE

²⁴ Indeed, Plaintiffs would later claim the publication of the '551 PCT Application formed the basis for Plaintiffs' state law claims in the present suit. Am. Compl. ¶¶ 61, 69, 75, 80, 83, 89. This email chain illustrates that Plaintiffs' [REDACTED].

²⁵ The Court should give no weight to the fact that Defendants did not name Mr. Vincent as a trial witness. ImStem, like most litigants, is trying to manage the amount of time that will be necessary for what will likely be a lengthy, complex trial. His emails, which may be brought into evidence via other witnesses and/or as party admissions, are sufficient to establish Astellas' understanding of [REDACTED] in 2014, prior to the statute-of-limitations window.

Plaintiffs seek to preclude the introduction of excerpts of their own privilege log. (Br. at 12-15), claiming the excerpts are not relevant and, even if they are, they must be precluded because they invite waiver of the attorney client privilege. (*Id.* at 13). The Court should reject this position.

As a starting point, there is no *per se* rule against admission of privilege logs. *See, e.g., Mut. Ins. Co. v. Murphy*, 630 F. Supp. 2d 158, 168 (D. Mass. 2009), as amended (July 2, 2009) (finding that a privilege log was admissible evidence, and noting that it likely constitutes a party admission); *Siemens v. Seagate Tech.*, No. SACV 06-788JVS ANX, 2009 WL 8762978, at *8 (C.D. Cal. Apr. 27, 2009) (finding that, in an inventorship dispute, a privilege log was admissible over objections premised on Fed. R. Evid. 401, 403, 807 and 1002). A privilege log – like any document – need only be relevant and probative of a fact at issue. *Compare Monterey Bay Military Hous., LLC v. Pinnacle Monterey LLC*, No. 14-CV-03953-BLF, 2015 WL 4593439, at *4 (N.D. Cal. July 30, 2015) (“This entry, by itself, is of little probative value”) with *Siemens v. Seagate Tech.*, No. SACV 06-788JVS ANX, 2009 WL 8762978, at *8 (C.D. Cal. Apr. 27, 2009) (finding that the privilege logs were probative of whether or not unreasonable delay existed).

That “probative” test is easily met here. On July 12, 2012, Drs. Wang and Xu filed the application that would mature into the ‘551 patent.²⁶ In May 2013, Astellas learned that [REDACTED]

[REDACTED]

[REDACTED]²⁷ On June 28, 2013, Dr. Kimbrel [REDACTED]

[REDACTED]²⁸ On that *same day*, June 28, 2013, Dr. Kimbrel emailed

²⁶ See generally Am. Compl. ¶ 47.

²⁷ See Ex. 13 (Lu email forwarding [REDACTED], dated May 21, 2013 (AIRM00093163)).

²⁸ See Ex. 14 (Kimbrel email dated June 28, 2013 (AIRM00031180)).

[REDACTED]

[REDACTED]²⁹ Indeed, the disputed privilege log will show that there were eight communications between June 2013 and September 2013 – more than four years before the Complaint – among [REDACTED]

[REDACTED]

In sum, the disputed evidence is probative of the fact that Plaintiffs knew that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The privilege log shows these things. It is probative of the Plaintiffs' knowledge which, if shown, defeats half the case. *See, e.g., Bowen v. Eli Lilly & Co.*, 408 Mass. 204, 207; 557 N.E.2d 739, 741 (1990) (holding that, for the statute of limitations period to be triggered, the plaintiff need not know every fact necessary to their claim, but must merely be aware of facts which would suggest that he/she has been injured).

There is more. As noted above, in February 2014, Plaintiffs [REDACTED]

[REDACTED].³⁰ The disputed privilege log indicates [REDACTED]

[REDACTED]

[REDACTED]³¹ Plaintiffs not only knew [REDACTED], they were already thinking about the [REDACTED]. The privilege log, again, is probative. *Cf. U.S. v. Hickey*, 596 F.2d 1082, 1089 (1st Cir. 1979) (evidence that “enhanced the

²⁹ See Ex. 9 (Excerpts of the Plaintiffs' Privilege Log) at line item #486.

³⁰ See Ex. 8 (Metadata re email from Fleishell to Kimbrel, dated February 21, 2014 (AIRM00037250)).

³¹ See Ex. 9 (Plaintiffs' Privilege Log, p. 10 (dated July 29, 2019) (at line item #309).

probability of guilt” was therefore probative); *see* Wright and Miller et al., 22A Federal Practice and Procedure § 5214.2 (2d ed.) (2019) (similar).

The probative value outweighs any prejudice to Plaintiffs. There is no unfair prejudice in the jury reaching the conclusion that Astellas knew it had suffered harm. Plaintiffs dodge this knowledge issue by claiming that Defendants are using privilege “as a sword to prove [Defendants’] case,” as if Defendants’ argument turned on the specific content of the legal advice given on that day. Not so. The probative evidence is the fact that Plaintiffs knew [REDACTED] [REDACTED]. The attorney-client privilege is not at issue. *See, e.g., Heron Interact, Inc. v. Guidelines, Inc.*, 244 F.R.D. 75, 78 (D. Mass. 2007) (“The shelter afforded by the [attorney-client] privilege, however, ‘only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney.’”). Simply put, a privilege log used to show that a client and an attorney were speaking is the same as mentioning that “someone had a conversation with an attorney,” which is “of course” not privileged. *Motorola Sols., Inc. v. Hytera Commc'ns Corp.*, 367 F. Supp. 3d 813, 817 (N.D. Ill. 2019).

The Defendants are not asking what the lawyers said, or what legal arguments the lawyers made, or what claims or defenses the lawyers raised. The advice rendered is not at issue. What matters is that Plaintiffs [REDACTED]. The fact that they were seeking legal [REDACTED] is surplusage. *Fidler v. Eastman Kodak Co.*, 714 F.2d 192, 199 (1st Cir. 1983) (holding that a plaintiff does not need to be aware of his/her legal injury for the statute of limitations period to begin).

To the extent there is prejudice to Plaintiffs, it can easily be mitigated. The Court may do so by giving a limiting instruction to the jury to this effect: focus on what the document suggests

Plaintiffs knew, [REDACTED]; disregard any inference regarding what the lawyers may have said. *Cf. Siemens v. Seagate Tech.*, No. SACV 06-788JVS ANX, 2009 WL 8762978, at *8 (parties agreed-to limiting instruction for privilege logs).

Plaintiffs have conceded as much. Despite filing the instant Motion, Plaintiffs are seeking to introduce the privilege log documenting communications between Defendants and their patent attorney, Susie Cheng. *See* Ex.15 (Plaintiffs' Proposed Trial Exhibit, PTX-369). Setting aside the profound inconsistency of Plaintiffs' position – the obvious goose/gander problem – Plaintiffs clearly contend that any potential prejudice to a party through introduction of such evidence is curable.³²

Plaintiffs' primary case to the contrary, *Monterey Bay*, should be given no weight.³³ In *Monterey Bay*, Judge Freeman concluded that the defendants' knowledge could only be "probed by knowing the substance" of the content of the conversation, thus requiring waiver. That was not true there – nor here. The only "content" required here is the indisputably non-privileged fact that Astellas sought legal advice [REDACTED]. That fact alone is probative of the time-bar, quite apart from the exact advice given during that conversation. The *Monterey Bay* court overemphasized the imagined inferences and underemphasized the underlying fact – that the party knew enough to seek counsel. Indeed,

³² Plaintiffs are likewise seeking to read deposition testimony from Defendants' patent attorney as well as several exhibits from this deposition which invite waiver of the attorney-client privilege. Plaintiffs also seek to enter a transcript and a recording of a telephone conference had by Defendants' trial counsel as evidence. Should the Court grant Plaintiffs' Motion regarding the privilege log, Defendants' respectfully request that the Court preclude proposed exhibit numbers PTX-344 to 348, 369, as well as the deposition designations of Attorney Susie Cheng, on the same grounds.

³³ No. 14-CV-03953-BLF, 2015 WL 4593439, at *4 (N.D. Cal. July 30, 2015). Aside from emanating from another district, the case can and should be set aside because it involves the highly fact-specific issue of evidence at trial. This Court has considerable discretion in regulating the conduct of trial. *See Borges v. Our Lady of the Sea Corp.*, 935 F.2d 436, 442 (1st Cir. 1991). This discretion includes making threshold relevance determinations and administering the Fed. R. Evid. 403 balancing test. *United States v. West*, 877 F.3d 434, 439 (1st Cir. 2017); *United States v. Maldonado-Garcia*, 446 F.3d 227, 232 (1st Cir. 2006).

given the strong corollary in this matter between the date Dr. Kimbrel [REDACTED] [REDACTED] and the communications listed on Astellas' privilege log – facts which simply were not present in *Monterey Bay* – the decision is distinguishable.³⁴ Accordingly, the *Monterey Bay* decision should be given no weight in this Court's analysis.

In short, the privilege logs are clearly probative of Plaintiffs' knowledge [REDACTED]

[REDACTED] prior to the statute of limitations' window and that Plaintiffs sat on their rights.

Defendants do not seek to offer or have the jury imply any legal advice or conclusions based on the privilege logs. Rather, the fact of Plaintiffs' knowledge is relevant to one of Defendants' affirmative defenses and any prejudice to the Plaintiffs is minimal, and is obviated with an appropriate curative instruction. Plaintiffs' motion should be denied.

V. CONCLUSION

For the reasons discussed herein, Plaintiffs' Omnibus Motion *in Limine* should be denied.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(c), Defendants respectfully request oral argument.

Defendants believe that oral argument will materially assist the Court in rendering a decision on the instant Motion.

³⁴ The First Circuit has decided that where the link between the inference the evidence evokes and the fact at issue is strong, the evidence is sufficiently probative to overcome a 403 objection. *U.S. v. Hickey*, 596 F.2d at 1089 ("the link between the sweater and mask and the robbery was strong, and the similarity of the hairs, while not affirmatively implicating Ferreira, "enhanced the probability of guilt" and was therefore probative.").

March 30, 2020

Respectfully submitted,

IMSTEM BIOTECHNOLOGY, INC., REN-
HE XU and XIAOFANG WANG,

By their Attorneys,

/s/ Timothy R. Shannon

Timothy R. Shannon, MA Bar # 655325
Martha C. Gaythwaite, MA Bar # 187650
VERRILL DANA LLP
One Portland Square
Portland, Maine 04101
(207) 774-4000
tshannon@verrill-law.com
mgaythwaite@verrill-law.com

Benjamin M. Stern, MA Bar # 646778
VERRILL DANA LLP
One Federal Street, 20th Floor
Boston, Massachusetts 02110
(617) 309-2600
bstern@verrill-law.com

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2020, I caused a true copy of the foregoing document to be served upon counsel of record via ECF.

/s/ Timothy R. Shannon
Timothy R. Shannon